JUN 2 4 2002

K012648

1 OF 2

510(k) Summary of Safety and Effectiveness

Submitter: Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Contact: Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
(480) 763-5300

Date of preparation: 8 August 2001

Name of device: Reprocessed External Fixation Devices

Common Name: External Fixation Devices, Fixation Appliance, Single/Multiple Component and Invasive Traction Component

Classification Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories

Reprocessed device(s):

MANUFACTURER	MODEL NUMBER	DESCRIPTION
HOWMEDICA	3362-1-304	OMEGA PLUS SIDEPLATE
HOWMEDICA	4920-1-100	TUBE-TO-ROD CLAMP
HOWMEDICA	4940-1-020	PIN-TO-ROD CLAMP
HOWMEDICA	4940-1-058	PIN-TO-ROD CLAMP
HOWMEDICA	5029-1-511	5 HOLE LIGHTWEIGHT ALLOY
HOWMEDICA	5029-2-110	10 HOLE LIGHTWEIGHT
HOWMEDICA	5029-2-111	10 HOLE LIGHTWEIGHT ALLOY
HOWMEDICA	5029-8-200	STEEL ROD
HOWMEDICA	5029-8-250	STEEL ROD
HOWMEDICA	5029-8-300	STEEL ROD
HOWMEDICA	5029-8-825	CARBON FIBER ROD
HOWMEDICA	5029-8-835	CARBON FIBER ROD
HOWMEDICA	5029-8-840	CARBON FIBER ROD
HOWMEDICA	5029-8-845	CARBON FIBER ROD
HOWMEDICA	5029-8-850	CARBON FIBER ROD
HOWMEDICA	5049-3-032	ARTICULATION COUPLING
HOWMEDICA	5150-2-380	CARBON FIBER ROD
HOWMEDICA	5150-2-391	CARBON TUBE
HOWMEDICA	5150-3-065	EXTERNAL FIXATION PIN CLAMP
HOWMEDICA	5151-3-065	EXTERNAL FIXATION PIN CLAMP

K012648

2 OF 2

Predicate device(s):	**K802722** Extended Ball Joint with Rod Hoffmann External Fixation System **K930836** Howmedica Mono-Tube™ External Fixation System **K971755** Hoffman II Compact External Fixation System
Device description:	External fixation devices are specially designed frames, clamps, rods, rod-to-rod couplings, pins, posts, fasteners, wire fixations, fixation bolts, washers, nuts, hinges, sockets, connecting bars and screws used for the management of bone fractures and reconstructive, as well as corrective, orthopedic surgery. Materials used include metal alloys, plastic and composites. These materials are chosen to address a wide range of fractures and applications as well as to allow for the appropriate amount of rigidity and stability.
Intended use:	External Fixation Devices are intended to be used for the fixation of supracondylar, or condylar fractures of the femur; for fusion of a joint; for surgical procedures that involve cutting the bone, for fixation of bone fractures; bone reconstruction; as a guide pin for insertion of other implants; or may be implanted through the skin so that a pulling force or traction may be applied to the skeletal system; and others may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.
Indications statement:	Reprocessed external fixation devices are indicated for use in patients requiring external skeletal fixation oand treatment of fractures, osteotomy, arthrodesis, correction of deformities, fracture revision, bone reconstruction procedures, limb lengthening, correction of bony or soft tissue deformities and segmental bony or soft tissue defects.
Technological characteristics:	The design, materials, and intended use of the Reprocessed External Fixation Device s are identical to the predicate devices. The mechanism of action of the Reprocessed External Fixation Device is identical to the predicate devices in that the same standard mechanical design, materials, shapes and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.
Performance data:	Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed External Fixation Devices. • Biocompatibility • Validation of reprocessing Performance testing demonstrates that Reprocessed External Fixation Devices perform as originally intended.
Conclusion:	In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (the Reprocessed External Fixation Device) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Don Selvey
Vice President Regulatory Affairs and Quality Assurance
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: K012623, K012634, K012645, K012648
Trade Name: Reprocessed External Fixation Devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT, KTW, JEC
Dated: April 3, 2002
Received: April 4, 2002

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notifications of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notifications. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012648

Device Name: Alliance Medical Corporation Reprocessed External Fixation Devices

Indications for Use: Reprocessed external fixation devices are indicated for use in patients requiring external skeletal fixation oand treatment of fractures, osteotomy, arthrodesis, correction of deformities, fracture revision, bone reconstruction procedures, limb lengthening, correction of bony or soft tissue deformities and segmental bony or soft tissue defects.

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012648

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use ___
(per 21 CFR 801.109)